

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 10 DEC 2004

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Applicant's or agent's file reference RPS6115-PCT	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/US04/01463	International filing date (day/month/year) 21 January 2004 (21.01.2004)	Priority date (day/month/year) 24 January 2003 (24.01.2003)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 9/14, 9/16, 9/48, 9/64 and US Cl.: 424/489, 490, 451, 456			
Applicant R.P. SCHERER TECHNOLOGIES, INC.			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 2 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

Date of submission of the demand

06 August 2004 (06.08.2004)

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Form PCT/IPEA/409 (cover sheet)(January 2004)

Date of completion of this report

28 November 2004 (28.11.2004)

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/01463

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☒ the description:
 - pages 1-46 as originally filed/furnished
 - pages* NONE received by this Authority on _____
 - pages* NONE received by this Authority on _____
- ☒ the claims:
 - pages 47-51 as originally filed/furnished
 - pages* NONE as amended (together with any statement) under Article 19
 - pages* NONE received by this Authority on _____
 - pages* NONE received by this Authority on _____
- ☒ the drawings:
 - pages NONE as originally filed/furnished
 - pages* NONE received by this Authority on _____
 - pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/figs NONE
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/01463

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 1-24 YES
Claims NONE NO

Inventive Step (IS)

Claims 1-24 YES
Claims NONE NO

Industrial Applicability (IA)

Claims 1-24 YES
Claims NONE NO

2. Citations and Explanations (Rule 70.7)

Claims 1-24 meet the criteria of PCT Article 33(2)-33(3) since the closest prior art, US 5,320,855 (ROCHE et al), US 4,851,226 (JULIAN et al) and US 5,019,563 (HUNTER et al) do not disclose nor fairly suggest a dispersion of crystals or granules of active substance in a lipophilic vehicle.

Claims 1-24 meet the criteria of PCT Article 33(4) since the claimed invention has industrial applicability in drug delivery applications.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: